In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

## I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement is filed:

| $\boxtimes$ | With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).  |
|-------------|--|
|             | Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.  |
|             | Before the mailing date of a first Office action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1). |

| This Informat | ion Disclosure Statement is filed:  |
|---------------|---|
|               | After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for the fee (\$180) set forth in 37 C.F.R. § 1.17(p) and any additional required fees. |
| This Informat | ion Disclosure Statement is filed:  |
|               | After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.  |
| The undersign | ned certifies that:   |
|               | Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.   |
|               | No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.   |
| II. Copies of | the Cited Items:  |
| $\boxtimes$   | Copies of all of the items listed on the attached Form PTO-1449 are enclosed.   |
|               | Copies of only the following items listed on the attached Form PTO-1449 are enclosed:   |
|               | Copies of those items which are marked with an asterisk (*) in the attached Form PTO-1499 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No, filed and relied upon in this application for an earlier filing date under 35 U.S.C § 120. See 37 C.F.R. § 1.98(d).   |

|          |                     | Copies of those items which are marked with an asterisk (**) in the attached Form PTO-1499 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.                |
|----------|---------------------|---|
| III. Co  | oncise              | Explanation of Relevance:   |
|          | $\boxtimes$         | A concise explanation of relevance of the items listed on Form PTO-1449 is not given.   |
|          |                     | A concise explanation of relevance of [some of] the items listed on Form PTO-1449 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references (copy attached). |
| IV. C    | Conclus             | sion:   |
| Citation | n of the            | e above documents shall not be construed as:  |
|          | 1.                  | an admission that the documents are necessarily prior art with respect to the instant invention;  |
|          | 2.                  | a representation that a search has been made, other than as described above; or   |
|          | 3.                  | an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).   |
|          |                     | spectfully requested that the Examiner indicate consideration of the cited returning a copy of the attached form PTO 1449 with initials or other appropriate  |
|          | <b>m</b> 1 <b>O</b> | · · · · · · · · · · · · · · · · · · ·   |

DATE: August  $\frac{9}{2}$ , 2001

Respectfully submitted,

Antoinette F. Konski Registration No.: 34,202

McCutchen, Doyle, Brown & Enersen, LLP Three Embarcadero Center, Suite 1800 San Francisco, California 94111

Telephone: (650) 849-4950 Telefax: (650) 849-4800



Form PTO-1449 Appl. No. 09/870,080 Docket No. 126881209900 RADEMAY Applicant(s) INFORMATION DISCLOSURE STATEMENT Charles A. NICOLETTE Group Art Unit: Unassigned Filing Date: May 30, 2001 (use several sheets if necessary)

## **U.S. PATENT DOCUMENTS**

|                   | (use s      | everal sheets if r | necessary)   |                   |       |          |                                  |
|-------------------|-------------|--------------------|--------------|-------------------|-------|----------|----------------------------------|
|                   |             |                    | U.S.         | PATENT DOCUMENTS  |       | A.       | ECEIVED                          |
| Examiner Initials | Ref.<br>No. | Date               | Document No. | Name              | Class | Subclass | Filing(Date)<br>(if appropriate) |
|                   | 1.          | 07/28/87           | 4,683,195    | Mullis et al.     |       | 1        | 1700                             |
|                   | 2.          | 07/28/87           | 4,683,202    | Mullis            |       |          | 1,00                             |
|                   | 3.          | 06/28/88           | 4,754,065    | Levenson et al.   |       |          |                                  |
|                   | 4.          | 01/24/89           | 4,800,159    | Mullis et al.     |       |          |                                  |
|                   | 5.          | 08/08/95           | 5,440,013    | Kahn              |       |          |                                  |
|                   | 6.          | 11/17/98           | 5,837,249    | Heber-Katz et al. |       |          |                                  |

## FOREIGN PATENT DOCUMENTS

| Examiner Initials | Ref.<br>No. | Date     | Document No. | Name   | Class | Subclass | Translation<br>YES NO |
|-------------------|-------------|----------|--------------|--|-------|----------|-----------------------|
|                   | 7.          | 08/01/96 | WO 96/23060  | The Government of the United States of America |       | ,        |                       |

## OTHER DOCUMENTS

(including author, title, date, pertinent pages, etc.)

| Examiner Initials | Ref.<br>No. | Title  |
|-------------------|-------------|--|
|                   | 8.          | Altman, J.D. et al., "Phenotypic analysis of antigen-specific T lymphocytes" (1996) <i>Science</i> <b>274(5284)</b> :94-96   |
|                   | 9.          | Bertoni, R. et al., "Human class I supertypes and CTL repertoires extend to chimpanzees" (1998) <i>J. Immunol.</i> <b>161</b> :4447-4455   |
|                   | 10.         | Boczkowski, D. et al., "Dendritic cells pulsed with RNA are potent antigen-presenting cells in vitro and in vivo" (1996) <i>J. Exp. Med.</i> <b>184</b> :465-472   |
|                   | 11.         | Bordignon, C. et al., "Retroviral vector-mediated high-efficiency expression of adenosine deaminase (ADA) in hematopoietic long-term cultures of ADA-deficient marrow cells" (1989) <i>PNAS USA</i> <b>86</b> :6748-6752 |
|                   | 12.         | Carter, B.J., "Adeno-associated virus vectors" (1992) Curr. Op. Biotechnol. 3:533-539  |
|                   | 13.         | Caruso, A. et al., "Flow cytometric analysis of activation markers on stimulated T cells and their correlation with cell proliferation" (1997) Cytometry 27:71-76  |
|                   | 14.         | Correll, P.H. et al., "Production of human glucocerebrosidase in mice after retroviral gene transfer into multipotential hematopoietic progenitor cells" (1989) PNAS USA 86:8912-8916                                    |
|                   | 15.         | Coulie, P.G., "Human tumour antigens recognized by T cells: new perspectives for anti-cancer vaccines?" (1997) <i>Molec. Med. Today</i> 3:261-268  |
|                   | 16.         | Culver, K. et.al., "Lymphocytes as cellular vehicles for gene therapy in mouse and man" (1991) PNAS USA 88:3155-3159   |
|                   | 17.         | Dharanipragada, R. et al., "The absolute configuration of an intermediate in the asymmetric synthesis of unusual amino acids" (1992) <i>Acta. Cryst.</i> <b>C48</b> :1239-1241   |

**EXAMINER:** 

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

|  |  | AUG 1 3  | 2001 5            |                                       |   | Sheet 2 of 4  |
|--|--|--|-------------------|---------------------------------------|---|---|
| Form PTO-1449  | PER STATE OF THE PER ST | T CE TO STATE OF THE STATE OF T | Docket No. 12     | 6881209900                            | Appl. No. 09/870,080  |   |
| INFORMAT<br>ST   | TON DIS  | CLOSUF<br>NT   | A BRILL           | Applicant(s)                          | Charles A. NI   | COLETTE AUG 1 4 2001  Group Art Unit: Unassigned 1                  |
| (use sever   | ral sheets if n  | ecessary)  |                   | Filing Date: Ma                       | ay 30, 2001   | Group Art Unit: Unassigned 7  |
| 18. D  |  | gada, R. et  | al., "Synt        | hetic linear and                      | cyclic glucagon antagon   | ists" (1993) Int. U. Penille Protein                                |
| P  | Perkin Tran  | s. <b>1(9)</b> :168  | 7-1689            |                                       |   | mimetics" (1989) J. Chem. Soc.                                      |
| m  | nethod to id   |  | lidate CT         |                                       |   | te (CTL) lysis, a more sensitive etected MHC class I stabilization" |
|  |  | t al. "Cell-s<br>liochem. <b>57</b>  |                   |                                       | eins via glycosyl-phospha                                       | atidylinositol structures" (1988)                                   |
|  |  |  |                   | ecific ELISPOT<br><b>160</b> :181-189 | assay single cell analys  | is of IL-2, IL-4 and IL-6 producing                                 |
| d  | erivatives o   | containing a   | aspartic a        | icid or norleucir                     | ne" (1990) J. Org. Chem.  |   |
| (1   | 1982) <i>Life</i> 3  | Scienc <b>ė</b> s <b>3</b> 1   | <b>1</b> :189-199 | 9                                     |   | ia amino acid side chain groups"                                    |
|  |  |  |                   |                                       | molecular design of rece<br>siderations" (1990) <i>Bioc</i>     | ptor-selective peptide ligands:<br>hem J. <b>268</b> :249-262       |
| ta   | andem SH2  |  | of ZAP-70         |                                       |   | ased activation motifs: The motifs with varying affinity" (1995)    |
| 27. Jo   | ones, R.C.   |  | Ward, "A          |                                       | steres: imidazolines in p                                       | seudopeptide chemistry" (1988)                                      |
| 28. K  | ahn, M. an   | d S. Berter  | nshaw, "T         | he incorporation                      | n of β-turn prosthetic uni<br>18):2317-2320                     | ts into merrifield solid phase                                      |
| 29. K  | arlsson, S.  | et al., "Sta   | ble gene          |                                       | sue-specific expression   | of a human globin gene using  |
|  |  |  |                   |                                       | g for a shared human me<br>PNAS USA <b>91(9)</b> :3515-         | elanoma antigen recognized by<br>3519                               |
| 31. K  |  |  |                   |                                       |   |   |
| ba   |  |  |                   |                                       |   |   |
|  |  |  | carboxylic acid   | •                                     | napeptides derived from L-cysteine inducing dipeptide analogue" |   |
| 34. Kemp, D.S. and B.R. Bowen, "Conformational analysis of peptide-functionalized diacylaminoepindolidiones ¹H NMR evidence for β-sheet formation" (1988) <i>Tetrahedron Lett.</i> 29 5082 |  |  |                   |                                       |   |   |
| di   | iaza-cycloc  | leca-2, 7-di   | one The           |                                       | , γ-diaminobutyric acid ar                                      | 3(S)-amino-10(R)-carboxy-1, 6-<br>nd D-glutamic acid: A β-turn      |

**EXAMINER:** 

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

|              | AUG P 3 2001   |   | PTO/SB/08 (2/92)  Sheet 3 of 4   |  |  |  |  |
|--------------|--|---|--|--|--|--|--|
| Form PTO-144 | 13.00  | Docket No. 126881209900   | Appl. No. 09/876,680CE/VE  |  |  |  |  |
|              | ATION DISCLOSURE<br>STATEMENT  | Applicant(s)  Charles A   | Appl. No. 09/876,680 CE/VE   |  |  |  |  |
| (use se      | veral sheets if necessary)   | Filing Date: May 30, 2001   | Group Art Unit: Unassigned   |  |  |  |  |
| 36.          | Kemp, D.S. and T.P. Curran, "( <sup>4,8</sup> ]-ridecane, 1 the preferred co OR (n=1 to 4) and α-temp –L-A formation" (1988) <i>Tetrahedron</i>  |   | s peptide conjugates $\alpha$ temp-L-(Ala) <sub>n</sub> -Me studies of templates for $\alpha$ -helix |  |  |  |  |
| 37.          | 4. Practical synthesis of 4-(alky templates" (1989) J. Org. Chem   |   | ct-3-enes (ben derivatives)as γ-turn   |  |  |  |  |
| 38.          |  | mmunications: A simple technique for us type 5" (1988) Virology <b>163</b> :614-61                              |  |  |  |  |  |
| 39.          | Hormone Res. 23:451-482  | nes to the chemical synthesis of peptid   |  |  |  |  |  |
| 40.          |  | d angiotensin converting enzyme inhib<br>xylic acid derivatives" (1984) <i>J. Takeda</i>                        |  |  |  |  |  |
| 41.          | Mosier, D.E. et al., "Resistance to human immunodeficiency virus 1 infection of SCID mice reconstituted with peripheral blood leukocytes from donors vaccinated with vaccinia gp160 and recombinant gp160" (1993) PNAS. USA 90:2443-2447 |   |  |  |  |  |  |
| 42.          | Muzcyzka, "Use of adeno-associated virus as a general transduction vector for mammalian cells" (1992)<br>Curr. Top. Microbiol. Immunol. <b>158</b> :97-129   |   |  |  |  |  |  |
| 43.          | Nagai, U. and K. Sato, "Synthe<br>Tetrahedron Lett. 26(5):647-65   | sis of a bicyclic dipeptide with the shap   | oe of β-turn central part" (1985)  |  |  |  |  |
| 44.          | Nair, S.et al., "Soluble proteins  | delivered to dendritic cells via pH-senses in vitro" (1992) <i>J. Exp. Med.</i> 1 <b>75</b> :60                 |  |  |  |  |  |
| 45.          |  | synthesis of a protein β-turn mimetic"  |  |  |  |  |  |
| 46.          |  |   |  |  |  |  |  |
| 47.          |  | s" (1998) Nature Med. 4(5 Suppl.):525   | 5-531  |  |  |  |  |
| 48.          |  |   |  |  |  |  |  |
| 49.          | Parker, K.C. et al. (1995) "Peptide Birding to MHC Class 1 Molecules: Implications for Antigenic Peptide Prediction" Immunol. Res. 14:34-57  |   |  |  |  |  |  |
| 50.          | 50. Parkhurst, M.R. et al., "Improved induction of melanoma-reactive CTL with peptides from the melanoma antigen gp100 modified at HLA-A*0201-binding residues" (1996) <i>J. Immunol.</i> <b>157</b> :2539-2548                          |   |  |  |  |  |  |
| 51.          |  |   |  |  |  |  |  |
| 52.          |  | or the analysis of relapse and marrow etrovirus-mediated gene transfer" (199                                    |  |  |  |  |  |
| 53.          | Rouse, R.J.D. et al., "Induction   | in vitro of primary cytotoxic T-lymphoc<br>(1994) <i>J. Virol.</i> <b>68(9)</b> :5685-5689                      |  |  |  |  |  |
| 54.          | Salazar, E. et al., "Agonist pept<br>antigen stimulates production of<br>efficiently than cognate peptide  | tide from a cytotoxic T-lymphocyte epit of TC1-type cytokines and increases ty (2000) Int. J. Cancer 85:829-838 | rosine phosphorylation more  |  |  |  |  |
| 55.          | Samanen, J. et al., "5,5-dimeth  | ylthiazolidine-4-carboxylic acid (DTC)  | as a proline analog with restricted  |  |  |  |  |

| F | X | Α | M | Ш | V | F | R: |  |
|---|---|---|---|---|---|---|----|--|
|   |   |   |   |   |   |   |    |  |

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

|         |   | Tilling Date. May 50, 2001  | Group Art Sint. Sinussigned     |  |  |  |  |  |  |
|---------|---|---|---------------------------------|--|--|--|--|--|--|
| (use se | everal sheets if necessary)   |   | - 0(                            |  |  |  |  |  |  |
|         | conformation" (1990) Int. J. Peptid   | de Protein Res. <b>35</b> :501-509  |                                 |  |  |  |  |  |  |
| 56.     | Schlesinger, S. and T.W. Dubensky, Jr., "Alphavirus vectors for gene expression and vaccines" (1999)  |   |                                 |  |  |  |  |  |  |
|         | Curr Opin Biotechnol. 10(5):434-439   |   |                                 |  |  |  |  |  |  |
| 57.     |   | Sette, A. et al., "The relationship between class I binding affinity and immunogenicity of potential cytotoxic T cell epitopes" (1994) <i>J. Immunol.</i> <b>153(12)</b> :5586-5592 |                                 |  |  |  |  |  |  |
| 58.     |   | of HLA-A2.1-transgenic mice specific for  | or henatitis C viral pentides   |  |  |  |  |  |  |
| .   00. |   | ns carrying HLA-A2.1" (1995) J. Immur   |                                 |  |  |  |  |  |  |
| 59.     |   | HLA-B7 binding peptides in the EBV-   |                                 |  |  |  |  |  |  |
|         | BZLF-1 proteins detected in the M   | 1HC class 1 stabilization assay. Low p  | roportion of binding motifs for |  |  |  |  |  |  |
| 0.0     | several HLA class 1 alleles in EBI  | NA-1" (1995) Int. Immunol. <b>7(4)</b> :653-66  | 3                               |  |  |  |  |  |  |
| 60.     | Tan, L. et al., "An improved asser  | nbly assay for peptide binding to HLA-I   | B*2705 and H-2K*class I MHC     |  |  |  |  |  |  |
|         | molecules" (1997) J. Immunol. Me  | eth. <b>209(1)</b> :25-36   |                                 |  |  |  |  |  |  |
| 61.     | Tanguay, S. and J.J. Killion, "Dire   | ct comparison of ELISPOT and ELISA  | -based assays for detection of  |  |  |  |  |  |  |
|         |   | " (1994) Lymphokine Cytokine Res. 13  |                                 |  |  |  |  |  |  |
| 62.     |   | tent antitumor CTL responses by recor   | mbinant vaccinia encoding a     |  |  |  |  |  |  |
|         | melan-A peptide analogue" (2000) <i>J. Immunol.</i> <b>164(2)</b> :1125-1131  |   |                                 |  |  |  |  |  |  |
| 63.     |   | ogenicity of peptides bound to MHC cla  | iss I molecules depends on the  |  |  |  |  |  |  |
|         | MHC-peptide complex stability" (1   |   |                                 |  |  |  |  |  |  |
| 64.     |   |   |                                 |  |  |  |  |  |  |
|         |   | e" (1983) <i>J. Immunol.</i> <b>131(3)</b> :1312-131  |                                 |  |  |  |  |  |  |
| 65.     | Wilchek, M. and E.A. Bayer, "The   Biochem. 171:1-32  | avidin-biotin complex in bioanalytical a  | applications (1966) Ariai.      |  |  |  |  |  |  |
| 66.     |   | sing a self-replicating RNA vaccine" (19  | 100) Not Med 5/7):823-827       |  |  |  |  |  |  |
| 67.     |   |   |                                 |  |  |  |  |  |  |
| 67.     | Zabrocki, J.et al., "Conformational mimicry. 1. 1,5-disubstituted tetrazole ring as a surrogate for the cis amide bond" (1988) <i>J. Am. Chem. Sci.</i> <b>110</b> :5875-5880 |   |                                 |  |  |  |  |  |  |
| 68.     |   |   | 1991) Int. I. Pen. Protein Res  |  |  |  |  |  |  |
| 00.     | Zechel, C. et al., "Synthetic glucagon antagonists and partial agonists" (1991) <i>Int. J. Pep. Protein Res.</i> <b>38(2)</b> :131-138  |   |                                 |  |  |  |  |  |  |
| 69.     |   | ipheral tolerance to a T cell epitope by  | heteroclitic antigen analogues" |  |  |  |  |  |  |
| 03.     | (1998) J. Immunol. <b>161(4)</b> :1705-1  |   | note: conto anagon analoguo     |  |  |  |  |  |  |
| 70.     |   | n of endogenous peptides to MHC clas  | ss I-restricted cytotoxic T     |  |  |  |  |  |  |
| ''      |   | mutant T2 cells" (1993) J. Immunol. 15  |                                 |  |  |  |  |  |  |

| EXAMINER: | DATE CONSIDERED: |
|-----------|------------------|
|           | <u> </u>         |

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.